

DEPARTMENT OF THE ARMY
MEDICAL DEPARTMENT ACTIVITY
FORT HUACHUCA, ARIZONA 85613-7040

MEDDAC Memorandum
No. 750-2

1 February 2005

Maintenance of Supplies and Equipment
REPAIR AND SERVICE OF MEDICAL/DENTAL EQUIPMENT

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1. HISTORY: This issue publishes a revision of this publication.

2. PURPOSE: To establish the Commander's policies, procedures, responsibilities and guidelines for efficient and timely repair and services of Medical/Dental Equipment.

3. APPLICABILITY: This memorandum applies to the maintenance of all Medical/Dental equipment assigned to the Ft Huachuca MEDDAC/DENTAC and the satellite clinics for which they provide support.

4. REFERENCES:

4.1 AR 25-400-2, The Army Records Information Management System

4.2 AR 40-61, Medical Logistics Policies and Procedures

4.3 AR 70-25, Use of Volunteers as Subjects of Research

4.4 AR 735-5, Policies and Procedures for Property Accountability

4.5 TB MED 750-1, Maintenance of Medical Equipment

*This memorandum supersedes MEDDAC Memo 750-2, 21 Feb 01

4.6 DA PAM 738-750, The Army Maintenance Management System

4.7 TB 38-750-2, Maintenance Management Procedures for Medical Equipment

4.8 TM 8-6500-001-10-PMCS, Operator's Preventive Maintenance Checks and Services for Reportable Medical Equipment

4.9 MEDDAC Memo 700-7, Loan of Government Equipment and Supplies to Civilian Installations

4.10 Comprehensive Accreditation Manual for Hospitals, Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

5. RESPONSIBILITIES:

5.1 Users/Operators and Supervisors. Medical equipment users/operators and supervisors must ensure that operation maintenance tasks are performed in accordance with manufacturer's instructions and TM 8-6500-001-10-PMCS.

5.2 The equipment operator is responsible for ensuring equipment meets infection control standards; is labeled with a Biohazard Label noting which parts of the machine can not be disinfected; and that operator maintenance is performed IAW manufactures instructions. Equipment submitted for repair that is found to be unclean will be returned to the user for cleaning prior to being serviced by the Clinical Engineering (CE) Section (SES). Maintenance personnel shall wear personal protection equipment to repair or access areas the user is unable to disinfect.

5.3 Equipment operators are responsible for ordering and replacing accessories and parts not requiring tools. Extensive disassembly, critical alignment or adjustment after installation will be completed by Clinical Engineering. User replacement parts and accessories include, but not limited to: hand pieces, transducers, batteries, filters, lamps, etc.

5.4 Using activities (Units, Clinics, ETC.) are not permitted to request Technical Inspection (TI classification) of medical/dental equipment when such equipment is excess to their needs. The item will be turned in to Chief, Equipment Management Branch (EMB) who will determine if a TI is required.

5.5 Clinic NCOIC's are responsible for training their subordinates in the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Environment of Care (EOC)

Standards pertaining to the Medical Equipment Management Plan (MEMP). Clinic SOP's, Emergency Preparedness Plans, and Training shall include the issues outlined in Appendix A of this memorandum.

5.6 The Clinical Engineering Section is responsible for the repair, preventive maintenance, calibration and electrical safety testing of all Medical/Dental equipment assigned to the Ft Huachuca MEDDAC/DENTAC and their satellites.

6. PROCEDURES:

6.1 Work Request Procedures: Work orders for equipment that has not been accounted for on the property book will not be accepted until the equipment is picked up on the property book. In an emergency the work order may be processed by using the requesting customers ID.

6.2 EMERGENCY SERVICES:

6.2.1 During normal duty hour's emergency requests will be accepted in person or by telephone from the responsible section NCOIC or his/her designated representative.

6.2.2 After hours and on weekends/holidays emergency requests will be made through the AOD in the PTC. The AOD is the only individual authorized to contact the CE technician on-call. Procedures for requesting emergency work orders are contained in the AOD book.

6.2.3 Work will be accomplished as soon as practical and the on-call technician will ensure that a follow-up work request from DMLSS is initiated so that parts and man-hours expended can be accounted for.

6.3 When unusual delays in accomplishing work are encountered the user will be informed.

6.4 PRIORITIES: It is the responsibility of the hand receipt holder to inform the Clinical Engineering Branch of Equipment requiring high priority repair consideration based on the use of equipment to sustain life, level of patient care for the clinic/unit and importance the equipment has regarding the mission of the unit or clinic when services are required.

6.5 REQUEST FOR REPAIRS: The user will be required to transport equipment to the Clinical Engineering Section and to pick it up upon completion of repairs. Installed and/or bulky equipment

will be repaired on site. At no time will repairs be made to equipment when it is being utilized to diagnose a patient or when a patient is connected to it. The Clinical Engineering Branch will not make repairs or service equipment, which does not meet infection control standards for cleanliness.

6.6 SHOP REPAIRS: The user will be given a copy of the Maintenance Work Order for items delivered to the Clinical Engineering Branch. This copy acts as a hand receipt for the user while the equipment is in maintenance. User must return this copy in order to claim his/her equipment.

6.7 The clinic/unit NCOIC will request a Maintenance Work Order for each item of equipment to be repaired, (like items which do not appear on the users hand receipt, may be grouped on one request) to the Clinical Engineering Branch. If the equipment is delivered to the Clinical Engineering Office, a DMLSS Maintenance Work Order will be initiated by the Supply/Work order Clerk.

6.8 All work requests will be submitted to the Clinical Engineering Section Supply Technician. Work requests will not be given directly to Medical Equipment Repairer except in the case of Emergency repairs.

6.9 The following information will be provided to Clinical Engineering so that a DMLSS Maintenance Work Order can be completed:

6.9.1 The ECN for the piece of equipment. This can be found on the upper left corner of the white bar code sticker attached to the equipment.

6.9.2 The location where the equipment can be found.

6.9.3 The service being requested ensuring that you are specific as to what is the problem with the equipment.

6.9.4 If the equipment requiring repair is too large to deliver to the maintenance shop, a telephonic request may be made at which time the user must provide an ECN number, brief description of the malfunction and where the equipment is located.

6.10 WAIVERS: A Memorandum will be initiated by the Clinical Engineering Section and forwarded to the hand receipt holder when equipment repair estimates would exceed the Maximum Expenditure

Limit (MEL) or when the MEL has been reached or exceeded. The hand receipt holder must determine whether the item needs to be repaired or turned in. If the decision is to have the item repaired, the request must have a waiver signed by the appropriate Commander and the approved waiver must be received prior to repairs being accomplished.

6.11 CONTRACTUAL SERVICES: The Chief, Equipment Management Branch or his representatives are the only personnel authorized to contact Civilian Firms, Manufacturers, or Contractors for repair service. (Any other personnel contacting outside repair services will be subject to billing for all costs incurred).

6.12 IN-SERVICE TRAINING: The Clinical Engineering Section will provide in-service maintenance related training to the user upon written request. Training consisting of clinical applications must be requested through Mobilization/Education/Training/Security Division. Users requesting training should include the Name, Manufacture and Model number of the item they are requesting training on, proposed time, location and date. The Chief Medical Equipment Maintenance Branch along with the NCOIC or OIC of the requesting activity will schedule the required training. A Specific training outline is provided in Appendix A of this memorandum.

6.13 SCHEDULED SERVICES:

6.13.1 The Chief, Equipment Management Branch schedules preventive Maintenance, Calibration, Inspection and Special Parts Replacement. During the month prior to the scheduled due date the Chief Equipment Management Branch will forward to the Hand Receipt Holder a list of items due for scheduled services. The hand receipt holder is to return signed copies of the Memorandum and Equipment Listing (with equipment location annotated along the left side) to the Medical Equipment Management Branch NLT the 25th of the month. The hand receipt holder or designated person shall locate all items on the list. This is to save time in locating them when the Medical Equipment Repairer arrives to perform required services. The Clinical Engineering Section is to be notified of any items that have been turned-in, transferred, or on loan to another hand receipt holder or activity.

6.13.2 After equipment has been serviced, the hand receipt holder will acknowledge services by signing the completed service request. Scheduled service request should be maintained on file for 2 years.

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6.14 NON LOCATED EQUIPMENT: Items that cannot be located by the Medical Equipment Repairer during services will be reported to the hand receipt holder and input as such to the Defense Medical Logistics Standard Support (DMLSS) Scheduled Work Order for each item not located. The Property Management Officer will be notified thru DMLSS. The hand receipt holder will have three working days in which to notify the Clinical Engineering Section of the location, after three days if the hand receipt holder has not located the item(s) the hand receipt holder will initiate a Report of Survey DA Form 4697 IAW AR 735-5.

6.15 PERSONAL EQUIPMENT:

6.15.1 Personally owned equipment will not be serviced or repaired by the U.S. Army. (AR 40-61 Chapter 2)

6.15.2 Civilian Physicians are not authorized to utilize personally owned equipment in Army facilities. (Property Management Bulletin 8-93 dated 28 July 93.)

6.15.3 Equipment brought into medical treatment facilities must comply with AR 40-61, Chapter 2, para 2-11. Clinical Engineering must inspect all medical equipment prior to use on any patient.

6.16 EQUIPMENT LOANS:

6.16.1 It is the policy of Ft Huachuca MEDDAC not to loan Government equipment to civilian institutions except for declared emergency situations and upon written approval of the MEDDAC/DENTAC Commander.

6.16.2 MEDDAC Memo 700-7 outlines the procedures and responsibilities relative to emergency loans of Government equipment to civilian institutions.

6.16.3 The Equipment Management Branch will be notified prior to the loan of any Medical/Dental equipment.

6.17 EQUIPMENT DEMONSTRATIONS AND EVALUATIONS of Medical/Dental Equipment. Procedures for demonstrations, evaluations, and aeromedical suitability determinations:

6.18 MATERIEL DEMONSTRATIONS. Demonstrations shall consist of the exhibit, use, or application of an item by the vendor. They do not involve action by Army personnel beyond observing the operations or use of the product by the vendor. (Equipment demonstrations do not involve patients.)

6.18.1 Commanders of Army Medical or Dental Activities may approve demonstrations. Activities may request basic product information from U.S. Army Medical Department Board (USAMEDDBD) prior to approving a demonstration. USAMEDDBD will provide information on file concerning user experience, acceptability, maintainability, and results of prior evaluations.

6.18.2 No endorsements or statement of results or opinions will be provided to the vendor.

6.18.3 All expenses incident to the demonstration will be borne by the vendor. This includes costs of transporting the product and installation and operation.

6.18.4 A demonstration does not change the Federal Acquisition Regulation (FAR) or Department of Defense FAR Supplement requirements governing follow-on contracting actions. Close coordination with the supporting contracting office is necessary to avoid contracting violations or claims.

6.19 MATERIEL EVALUATION. A materiel evaluation is the use of an item by an activity. The primary purpose is to determine whether that item or a similar item should be requested for purchase and use. (Material Evaluations may include use of the equipment on patients.) The evaluation period will be of limited duration, usually not to exceed 30 days. This limitation is necessary so as not to imply an acceptance or obligation to the vendor. Evaluations longer than 30 days must receive MACOM approval.

6.19.1 Commanders of Army Medical or Dental Activities may approve evaluations when a demonstration is not expected to be adequate for determining the desirability of the item for future use.

6.19.2 If not already part of a demonstration, the evaluation process will begin with a request to USAMEDDBD for product information.

6.19.2 If not already part of a demonstration, the evaluation process will begin with a request to USAMEDDBD for product information.

6.19.3 When a commander determines that an evaluation is still necessary after reviewing the USAMEDDBD product information, a written agreement between the activity and the vendor will be

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prepared. This will be done in coordination with the supporting property management officer and supporting contracting officer. The supporting contracting officer will execute this agreement.

6.19.4 Materiel evaluation agreements will include the following points: Items will be delivered, installed, operated, and removed at no cost to the Government. The Government will not be responsible for the loss, damage, or destruction of materiel while in its possession. Expenses for the return of materiel to the vendor after evaluation will be borne by the vendor. The vendor, at no cost, will provide special maintenance or operator training prior to the evaluation of the Government. The activity and individuals examining the item assume no obligation to furnish an oral or written report to the vendor on the results of the evaluation. Under no circumstances will reports be released to activities outside the Federal Government without prior written approval of TSG. The vendor will not make reference to the evaluation for advertising or other promotional purpose unless the information has been published or presented through recognized professional media, or its release has been specifically approved by TSG.

6.19.5 When an evaluated item is delivered, the property management officer will establish temporary informal property accountability. This property will be issued on a hand receipt to the principal hand receipt holder. The hand receipt and accounting records will be cleared on return of the materiel to the vendor following the evaluation. These property records (file number 1416-1b) will be maintained with the property book as prescribed by AR 25-400-2.

6.19.6 The evaluation should follow a simple plan. The plan should consider functional performance, improved capability and compatibility with existing systems, reliability, maintainability, safety, and overall value to the Government.

6.19.7 If volunteers are required for evaluation of a procedure, refer to AR 70-25.

6.19.8 The investigator will provide an evaluation report through their medical or dental activity commander with a copy forwarded directly to USAMEDDBD. The report should address the items in b above, in general terms, with a brief discussion of each. Details normally related to formal evaluations are not expected.

6.20 MATERIEL EVALUATIONS. Evaluations are formal investigations of materiel that may have an AMEDD-wide potential to improve health care or efficiency. They require evaluation protocols, milestone schedules, and progress reports. Evaluations should not be undertaken to support sole source purchases. Comparative evaluations of competitive equipment can be required to assure objectivity and evaluation of the best available materiel. Evaluations will be approved on a case-by-case basis. Demonstrations and evaluations will be considered prior to requesting an evaluation.

6.20.1 Commanders of medical and dental activities will submit evaluation requests through command channels to USAMEDDBD in accordance with MACOM procedures. Format guidance for request is provided in appendix B of AR 40-61.

6.20.2 On receipt of the request, USAMEDDBD will conduct an expanded materiel inquiry. The inquiry will include the following: Identification and analysis of other evaluations by other agencies, review for comparable materiel in the Federal supply system or on the commercial market, survey of user experience, and consideration of comparable items for concurrent evaluation.

6.20.3 USAMEDDBD will recommend to HQDA (DASG-HCL), WASHINGTON, DC 20310-2300, approval or disapproval of the evaluation request, to include evaluation of comparable items and possible field-testing.

6.20.4 On TSG approval, an evaluation site will be designated by USAMEDDBD in coordination with the appropriate MACOM.

6.20.5 USAMEDDBD will prepare an evaluation plan and milestone schedule in coordination with the designated evaluation activity.

6.20.6 The evaluation activity will accomplish the evaluation actions above, conduct the evaluation according to the approved evaluation plan, submit evaluation results to the USAMEDDBD, and participate with the USAMEDDBD as required in preparation of the evaluation report.

6.20.7 USAMEDDBD will prepare the evaluation report and submit it to HQDA (DASG-HCL), WASH DC 20310-2300.

6.20.8 TSG will review the evaluation report and act on recommendations as appropriate for potential AMEDD-wide use.

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6.21 Materiel inquiries. USAMEDDBD provides a comprehensive information service for medical materiel and for nonmedical materiel with medical implications. Inquiries may be submitted in writing to USAMEDDBD (Fort Sam Houston, TX 78234-6000) or by calling commercial (512) 221-5503/5145/2624 or DSN 471-5503/5145/2624.

6.21.1 Direct inquiries are encouraged. USAMEDDBD has access to extensive Government and civilian information systems.

6.21.2 USAMEDDAC does not endorse or recommend items. It provides information for use in resolving materiel requirements and for informed acquisition planning. When available, the following is provided:

6.21.3 Market survey information. This includes state-of-the-art developments, user experience data, user lists, list of comparable items, product literature, safety and cost information.

6.21.4 Test and evaluation data.

6.21.5 Stock and availability data, if standardized.

6.22 EQUIPMENT FAILURES/RECALLS/ALERTS/USER ERRORS

6.22.1 Equipment Failure/Serious Incident. Anytime a piece of medical equipment fails to operate while in support of a patient, and may have or did contribute to the improper care, injury, or death of a patient, the user is required to submit a DA Form 4106, Quality Assurance Risk Management Document along with a work order request to Clinical Engineering. Clinical Engineering must investigate the cause and report findings IAW the Safe Medical Devices Act of 1990 (SMDA).

6.22.2 Medical Device Recalls/Alerts. Clinical Engineering is responsible for informing hand receipt holders of any Medical Device Recalls/Alerts pertaining to equipment on their hand receipt. Samples of such notices are found in Appendix B of this memorandum.

6.22.3 Operator/User Related Equipment Errors. Clinical Engineering is responsible for conducting monthly reviews of all completed work orders. When evidence of possible Operator/User Related Equipment Error is found to have contributed to the cause of the equipment malfunction, a notice is sent to the hand receipt holder owning the equipment. Samples of such notices are

found in Appendix C of this memorandum. Hand receipt holders are required to respond to such notices IAW Appendix D of this memorandum.

6.23 VERIFICATION OF CALIBRATION LABELS

6.23.1 DD Form 2163, Medical Equipment Verification/Certification Label. The purpose of this label is to inform equipment users as to whether or not equipment is within calibration. Users are responsible for inspecting this label prior to each use of the equipment. If a label is found to be past the review date posted on the label, the user must remove the equipment from use and notify the Equipment Management Section.

6.23.2 DA Label 175, Defibrillator Energy Output Certification Label. The purpose of this label is to inform the equipment user of the actual Defibrillator output at a given setting. Users are responsible for inspecting this label prior each use of the Defibrillator. If a label is found to be past the review date posted on the label, the user must remove the equipment from use and notify the Equipment Management Section.

The proponent of this publication is Logistics Division. Users are invited to send comments and suggested improvements on DA Form 2028 directly to Logistics Division, ATTN: MCXJ-LO, Fort Huachuca, Arizona 85613--7040.

FOR THE COMMANDER:

OFFICIAL:

NOEL J. CARDENAS
MAJ, MS
Deputy Commander for
Administration

Robert D. Lake
Information Management Officer

DISTRIBUTION: Special one each except where noted

MCXJ-DP	MCXJ-DMM	MCXJ-DS-OB	HSBJ-RDC-Lab	MCXJ-DN-CMS
MCXJ-DR	HSBJ-CDR	MCXJ-CM-AMB	MCXJ-PM(2)	MCXJ-DS-OPT
MCXJ-DN-IC	MCXJ-CM-CC	MCXJ-DN-CMS	MCXJ-LO-MM(10)	
MCXJ-DS	MCXJ-LO-PB	MCXJ-DM(10)	MCXJ-DS-ENT	
MCXJ-METS	MCXJ-DS-ORT	HSBJ-RDC(2)		
MCXJ-RX	MCXJ-SWR-H	MCXJ-PACU		

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Appendix A
SAMPLE

JCAHO EOC TRAINING REQUIREMENTS
FOR MEDICAL EQUIPMENT USERS IN REGARDS TO
THE MEDICAL EQUIPMENT MANAGEMENT PLAN

Each clinic NCOIC is responsible for training their staff in the following areas:

Orientation and Education Program
Performance Standards for Staff
Emergency Procedures

1. NCOIC's must ensure that the clinic SOP contain requirements for a medical equipment orientation and education program. NCOIC's must give classes that address:

- a. capabilities, limitations, and special applications of equipment;
- b. basic operating and safety procedures for equipment use; and
- c. emergency procedures in the event of equipment failure.

2. Emergency Management Plans must include written procedures on

- a. specific procedures to take in the event of equipment failure;
- b. when and how to perform emergency clinical interventions when medical equipment fails;
- c. availability of backup equipment; and
- d. how to obtain repair services.
- e. information and skills necessary to perform assigned maintenance responsibilities (perform scheduled services); and
- f. processes for reporting and responding to medical equipment management problems (Recalls and Alerts) , failures (completion of Risk Management Documents DA Form 4016) , and user errors.

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3. Performance standards for staff (Staff shall be familiar with this memorandum and be capable of answering questions pertaining to):

- a. equipment management knowledge and skills required of staff,
- b. the level of staff participation in equipment management,
- c. the level of staff participation in monitoring and inspection activities,
- d. specific procedures for emergency and incident reporting that specify when and to whom reports are to be communicated, and
- e. equipment inspection (scheduled services), preventive maintenance and testing (INSP, PM, CAL, SPR) of medical equipment.

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Appendix B

Pertinent Medical Device Recalls/Alerts Memorandum SAMPLE
MEMORANDUM FOR MEDDAC Safety Committee

SUBJECT: Pertinent Medical Device Recalls/Alerts for the period
1 Sept through 30 Sept 1994

DISCUSSION: On 9-14-94, a notice was issued by Beckman Instruments in regards to the Synchron CX Cholesterol Calibrator. The purpose was to inform users of an incorrect set point on the product insert and calibrator diskette for the HDL cholesterol calibrator, lot number M305152. Users were advised to refer to the Synchron Cx system operating instructions to modify the set point for the defective lot number.

CONCLUSION: Provide user with corrective action instructions.

RECOMMENDATION: Ensure users of the device are following the manufacture instructions.

ACTION: A copy of the notice and instructions were forwarded to Mr. Sheilds in Pathology.

EVALUATION: An acknowledgment was received indicating that the notice and instructions have been posted and complied with.
STATUS: Issue closed

Chief Equipment Management Br.

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Appendix C
Operator/User Related Equipment Errors Memorandum SAMPLE

SUSPENSE: Date
Date

MCXJ-LO-CE

MEMORANDUM FOR NCOIC

SUBJECT: Operator/User Related Equipment Errors

1. The attached listing indicates that one or more equipment related failures occurred as a result of operator/user error within your clinic/activity during the month of FEB 04. This listing is based on an evaluation of the equipment for which users submitted a work order.

2. Each incident in which an equipment failure results from operator/user error needs to be documented to determine the cause. The cause of the error may be lack of documentation such as operator manuals, or lack of training on the use or maintenance of the specific piece of equipment. However, in each case equipment failure affect the safety of the patient and operator. Action must be taken to preclude a reoccurrence.

3. Document all equipment failures on the Information Collection and Evaluation System (ICES) Report submitted to the MEDDAC Safety Officer.

4. You are required to maintain a copy of this report along with your findings in the Maintenance Binder provided to your clinic marked as ARMIS File 738-750e.

5. Attached is a simplified user checklist that will assist you in investigating this matter and developing a correct solution and response. Please return the attached checklist to Medical Maintenance by the indicted suspense date.

6. Point of contact concerning this action is Chief, Equipment Management, extension 533-2836.

Chief, Logistics Division

Appendix C
User Related Equipment Errors Memorandum Sample

MCXJ-LO-CE (15-1a)

2 Oct 04

MEMORANDUM FOR MEDDAC Safety Committee

SUBJECT: User Related Equipment Errors for the period of 01 Sept through 30 Sept 2004

(0994-1)

DISCUSSION: Dental Operating Light: ECN: 0B5478
Runion Dental Clinic Mfg: Pelton & Crane Mdl: LFT-II
Complaint: No light.
CONCLUSION: Upon inspection, Clinical Engineering found that the light bulb was burnt out.
ACTION: Incident referred to NCOIC Runion Dental Clinic for corrective action.
EVALUATION: Operator Error. (lamps are user replaceable items)
STATUS: Open. Clinic NCOIC to instruct operators in the replacement of lamps and to report follow up comments to the safety committee.

(0994-2) ** REPEAT OCCURRENCE **

DISCUSSION: Dental Operating System ECN: 0B5389
Dental Clinic #1 Mfg: Pelton & Crane Mdl: Spirit
Complaint: No air to syringe tip.
CONCLUSION: Upon inspection, Clinical Engineering found a small piece of plastic clogging the tip. The plastic came from the sterilization bag. The user had poked the tip through the bag when attempting to remove it instead of cutting the bag open.
ACTION: Incident referred to Clinic NCOIC for corrective action.
EVALUATION: Operator Error. (this problem has surfaced due to the autoclaving of syringe tips)
STATUS: Open. Clinic NCOIC to instruct operators in the correct procedure for removing syringe tips from sterilization bags, and to report follow up comments to the safety committee.

Appendix D

SAMPLE

Operator/User Related Equipment Errors Checklist

Request response in writing to the Equipment Management Branch answering the questions listed below. These requirements are consistent with the JCAHO Standards.

Please use this checklist to address each of the following areas:

a. Enter the work order and incident number pertaining to the attached incident report:

MSCN: Incident #:

b. Discussion of the problem. (Complaint)

(1) (a) What was the equipment failure?

(b) Describe how the equipment failed and the operator's immediate action to correct the malfunction.

(2) Did the operator have a copy of the operator's manual? Yes No

(3) Was the operator trained on the piece of equipment as part of the Competency Based Orientation? Yes No

(4) Did the operator follow the instructions in the user's manual? Yes No

(5) Was operator maintenance being performed in accordance with the instructions included in the operator's manual? Yes No

c. Prior to implementing any corrective action, confirm that the corrective action is appropriate to the equipment failure.

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What action has the section initiated to preclude a reoccurrence of the equipment failure:

1. Do you need an operator's manual? Yes No
2. Did your investigation identify a need for training? Yes No
3. Have you documented the training? Yes No N/A

APPENDIX E
SAMPLE TEST AGREEMENT AND LICENSE

This Test Agreement and License is made as of the 7th day of September 19 2004, by and between Desert Mountain Medical 4614 N. Southern St. Phoenix, AZ 85014 (602)-274-7617 Fax: 602-274-7691 (Licensor) and Raymond W. Bliss Army Health Center Bldg: 45001 Fort Huachuca, AZ 85613-7040 (Licensee) and ending on the 7th day of December 2004.

WHEREAS, Licensor agrees to provide the following listed and/or described equipment(s) to Licensee for testing and evaluation purposes: (Equipment serial numbers will be listed when available.)

ARTHREX ARTHROSCOPY PUMP MODEL: 6300

TESTING SHALL BASICALLY CONSIST OF: (Be as specific as possible.)

Adaptability of the equipment to our working environment

EVALUATION SHALL BASICALLY CONSIST OF: (Explain or describe what is intended to be derived or achieved from the testing effort.)

DETERMINATION AS TO WHETHER LICENSEE WILL PURCHASE ITEM PER TEST AGREEMENT REGARDING SUCH EQUIPMENT FOR FUTURE USE.

It is further agreed as follows:

1. Licensor grants consent to Licensee to use the above-described equipment(s) for testing purposes as herein stipulated for the explicit purpose of evaluation. Licensor conveys no title to any equipment(s) herein described, and Licensee shall acquire no ownership rights or entitlements. Licensee shall not interface or connect any equipment(s) or configured systems without the express written consent of the Licensor. Such consent may be accomplished by addendum to this agreement. Only the Licensor shall accomplish Modification(s) to equipment(s) provided for testing purposes, unless otherwise explicitly authorized by addendum to this agreement.

2. All software, including, without limitation, all equipment and hardware supplied by Licensor software media, whether microfiche, paper, magnetic tape, disk, floppy disk, or other reproduction, shall at all times remain the property of Licensor. All software provided by the Licensor to Licensee in conjunction with tests and evaluations accomplished under this agreement shall be considered to contain all proprietary informational notifications for Licensor protection.

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In the event Licensee shall break this proprietary provision, Licensors shall be entitled to (1) injunctive relief, in addition to any other remedies provided by law, (2) the termination of this license, and (3) the immediate return of all equipment(s) and respective software to Licensors.

3. Licensee shall provide all test site facilities and utilities that are required for the conduct of any and all tests to be accomplished pursuant to this agreement.

4. Licensors shall be responsible for all transportation of equipment(s) provided by Licensors in conjunction with tests and evaluations under this agreement, to and from the initial test site(s). The Licensee shall incur no costs for transportation of those equipment(s) provided by the Licensors under this agreement, except as may further be provided by a conditional addendum to this agreement.

5. Licensee will assume no responsibility or liability for damages to or destruction of any equipment(s), to include all software herein described, provided under this agreement, except as may be caused by negligence or willful misconduct. Licensors shall be responsible for all maintenance and repair of provided equipment(s) except as occasioned by negligence or willful misconduct on the part of the Licensee.

6. Licensee shall at all times protect and safeguard information that the Licensors has identified as proprietary confidential in nature or as a Licensors's trade secret. Licensee may divulge such information only to those United States Government personnel directly involved in the tests and evaluations conducted pursuant to this agreement, and then only on a bona fide need-to-know basis.

7. The Licensors will not use any information or contributive reference relating to the tests and evaluations resulting from provisions of this agreement, for advertising purposes, to include the fact that the Licensee permitted, conducted, or participated in the respective tests and evaluations.

8. The release of information or data generated as a result of tests and evaluations conducted under provisions of this agreement to the Licensors, shall be the sole and unilateral decision of the Licensee. The Licensee shall not release information or data generated pursuant to this.

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agreement outside the United States Government without the express written consent of the Licensor.

9. Licensee's participation in this agreement shall in no way obligate Licensee to purchase any equipment, materials, or services from Licensor.

10. Licensor shall provide the above described equipment at no cost to Licensee for a term commencing on the date of delivery of the equipment (7 September 2004) to Licensee and ending on such date as Licensor shall elect (7 October 2004) Upon termination of this Test Agreement and License as provided herein, Licensee shall return the equipment to Licensor.

11. Office of Management and Budget exemption: Title 5, Code of Federal Regulations, Sections 1320-7(k) and (1).

IN WITNESS WHEREOF, the parties hereto have executed this TEST AGREEMENT AND LICENSE as of the date first above written.

LICENSOR:

LICENSEE:

BY: _____ BY: _____

TITLE: _____ TITLE: _____

Approved for legal sufficiency.
sufficiency.

Approved for legal

BY: _____ BY: _____

TITLE: _____ TITLE: _____

DATE: _____ DATE: _____

=====

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SAMPLE

Directorate of Contracting
2004
Installation Support Division
ATTN: ATZS-DKO-H
FT Huachuca, AZ 85613

2 SEPTEMBER

MEMORANDUM FOR Desert Mountain Medical ATTN: Gary Fragle
4614 N. Southern St. Phoenix, AZ 85014

Dear Mr.Fragle

Attached is a Test Agreement and License covering the terms and conditions relating to the test and evaluation of your firm's equipment that you desire this command to conduct.

Please review the contents of the Test Agreement and License, and if such meets your satisfaction, sign in the space provided for licensor. If appropriate, your legal counsel should also sign in the space provided.

The signed Test Agreement and License should be returned to the contracting office. Address correspondence to: Directorate of Contracting, ATTN: ATZS-DKI, Post Office Box 748, Fort Huachuca, Arizona 85613-0748. The Contracting Office will affix his signature, obtain the signature of legal counsel, if necessary, and return a copy of the duly executed document for your retention.

Any inquiry in conjunction with this matter should be directed to the Director Equipment Management Branch at Raymond W. Bliss Army Health Center, telephone number (520)533-3712.

Sincerely,

]

Contracting Officer

Attachment
Copy Furnished (w/attach):

Raymond W. Bliss Army Health Center (Director, Equipment
Management Branch Mr. Cage) - Fort Huachuca, AZ 85613

1 February 2005

MEDDAC MEMO 750-2

SAMPLE

SUSPENSE: 6 September 2004
2 September 2004

MCXJ-LO-MM

Director of Contracting
ATTN: ATZS-DKO-H
Contracting Officer
Ft Huachuca, AZ 85613

1. IAW ASR 70-1, request attached test agreement and license be reviewed, signed, and forwarded to Desert Mountain Medical 4614 N. Southern St. Phoenix, AZ 85014 (602)-274-7617 Fax: 602-274-7691.
2. The proposed testing period will be 7 September 1999 through 7 December 1999.

Director Equipment Management
Branch
MCXJ-LO-MM
533-2836